SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4921–4960

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia and National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, and its quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the quantity of alcohol contained therein; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (g), the article purported to be a drug, the name of which is recognized in an official compendium, and it was not packaged as prescribed therein; Section 502 (i) (3), the article was offered for sale under the name of another drug; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling.

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4921. Sobrin and Solfera tablets. (F. D. C. No. 35126. S. Nos. 40–628 L, 44–420 L, 49–432 L, 52–320 L.)

INFORMATION FILED: 8–20–53, Dist. N. J., against Scientific Aids Co., a partnership, Jersey City, N. J., and George Van Dyne and Maurice Van Dyne, partners; amended information filed 3–5–54.

ALLEGED VIOLATION: The information alleged that, within the period from 6–10–52 to 8–25–52, while a quantity of *Solfera tablets* was being held for sale, the defendants repackaged a number of the tablets under labels which failed to bear adequate directions for use, which act resulted in the tablets being misbranded.

The information alleged also that, between 8–22–52 and 10–13–52, the defendants shipped misbranded *Solfera tablets* and *Sobrin* from New Jersey to Massachusetts, New York, and Washington.

LABEL IN PART: (Btl.) "Sobrin Emetic Brand of Fluid Extract of Ipecac Alcohol 31% ½ oz. Distributed by Scientific Aids Co. Box 118 Jersey City 3, N. J. Directions: Put 30 drops of this fluid into the first drink only. Do not use any more drops during the next 24 hours, no matter how many more drinks are taken following the first drink. Use only as directed above and by directions accompanying bottle. Caution: Do not use in heart, liver, pregnancy, kidney or circulatory disease without consulting your physician" and "Solfera Tablets Directions: Take one tablet with water after each meal three times daily. Caution: Use only as directed. Contents: Ferrous Sulphate—Each tablet contains 5 grains U. S. P. 50 Tablets Indicated for secondary Anemia when due to Iron Deficiency. Distributed By Scientific Aids Company, Inc. Box 118 Jersey City 3, N. J."

ACCOMPANYING LABELING: (*Sobrin*) Circulars entitled "Instructions in English" and "Read What Happy Satisfied People Write After Using Our Famous Formula and Method."

CHARGE: *Sobrin.* 502 (a)—the labeling of the article, when shipped by the defendants, contained false and misleading representations that the article was an adequate and effective treatment for drunkenness; and 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling.

Solfera tablets. 502 (f) (1)—the labeling of the article, when shipped by the defendants and while held for sale by the defendants, failed to bear adequate directions for use for the purpose and condition for which it was intended, namely, for use in the treatment of persons suffering from delayed menstruation. The article was offered for that condition and purpose in magazine advertisements sponsored by the defendants.

DISPOSITION: On 9–9–53, the defendants entered pleas of not guilty. Thereafter, they filed motions to dismiss the information and to suppress evidence thereunder on the grounds (1) that the information was based on a statute that was confusing and ambiguous; (2) that the method by which the Government obtained its evidence precluded any criminal action against the defendants; (3) that the information was founded upon evidence illegally acquired in derogation of Section 703 of the Act and in violation of defendants' constitutional rights; (4) that the information violated defendants' privilege of immunity under Section 703; (5) that having secured the evidence used against defendants under a libel, it was unlawful for the Government to use that evidence in a criminal prosecution of defendants; and (6) that the matters alleged in the information were res adjudicata.

The above-mentioned motions came on for hearing before the court; and, on 1–19–54, the court, having determined that the grounds urged in support thereof were without merit, entered orders denying the motions. With respect to the motion to suppress evidence, the court, in an opinion reported in United States v. Scientific Aids Co., et al, 117 F. Supp. 588 (D. N. J. 1954), found that the inspections were made under Section 704 during the usual business hours without objection by the defendants who, at the inspector's request, voluntarily surrendered to him samples of their product, specimens of their labels, and copies of their advertising, and that the defendants made the pertinent records available and acquiesced in the inspectors' examination. The court further held that Section 703 was not applicable and that defendants' constitutional rights had not been violated.

On 3–5–54, the information was amended; and, on 4–9–54, the individual defendants entered pleas of guilty. Thereafter, on 5–28–54, the individual

defendants filed a motion for leave to withdraw their pleas of guilty and enter pleas of not guilty. This motion was denied on 7–13–54. On 8–11–54, the court fined each individual defendant $1,000 and sentenced each to imprisonment for 6 months. The court suspended this sentence and placed the defendants on probation for 2 years. The partnership was dismissed as a defendant upon the Government's motion at the time of sentencing.

On 8–20–54, the individual defendants filed a notice of appeal to the United State Court of Appeals for the Third Circuit; and, on 12–28–54, this court, after considering arguments and briefs of counsel, entered an order affirming the judgment of the lower court.

4922. Lady Bountiful device. (F. D. C. No. 38480. S. No. 36–961 M.)

QUANTITY: 179 individually cartoned devices at New York, N. Y.

SHIPPED: 9–3–55, from Hollywood, Calif., by Atlanta Corp.

ACCOMPANYING LABELING: A brochure entitled "The story of Lady Bountiful" and a circular designated "Lady Bountiful News November 22, 1951."

RESULTS OF INVESTIGATION: The device consisted of two rubber-edged plastic cups, one of which was slightly larger than the other, and a long rubber hose attached to a specially designed aspirator for attachment to the water faucet.

In use, the plastic cup would be pressed against the chest so that it enclosed one of the breasts and the rubber edge formed an air-tight seal against the chest. The small compact pump fitted over the cold water faucet; the cold water flowed through the specially designed pump and down the drain, never touching the breast but creating a controlled vacuum directed into the plastic cup. By applying and relaxing the thumb on the opening at the top of the rubber tube, the vacuum in the cup exercised the breast by contraction and relaxation.

LIBELED: 10–6–55, S. Dist. N. Y.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped and while held for sale, contained false and misleading representations that the article was effective for increasing the size of the breasts, for providing shape, growth, and expansion for underdeveloped or sagging breasts so that they would become full, round, and firm; and for improving the tone of the breast tissues; and 502 (j)—the article was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in its labeling since the directions appearing therein recommended and suggested that the device be used from 10 to 25 minutes a day for a period of 2 or 3 months, whereas when used as recommended and suggested, the device may be dangerous where an unsuspected cancer is present or where other pathological conditions may be present.

DISPOSITION: 12–28–55. Default—portion delivered to Food and Drug Administration and remainder destroyed.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

4923. H–17 and physiological salt solution. (F. D. C. No. 38421. S. Nos. 13–116/7 M.)

QUANTITY: 37 50-cc. vials of *H–17* and 37 50-cc. vials of *physiological salt solution* at Philadelphia, Pa.

SHIPPED: 5–10–55, from Los Angeles, Calif., by Rene Labhardt.